

## **REMARKS**

Applicants have carefully reviewed the Office Action mailed January 9, 2008, prior to preparing this paper. Currently, claims 1, 5-16, 20, 24-41, 44 and 45 are pending in the application, wherein claims 1, 5-16, 20, 24-41, 44 and 45 have been rejected. Claims 1, 20, 36, 39 and 45 have been amended with this paper. Support for these amendments may be found, for example, at lines 9-12 of page 3 and line 3 of page 5 through line 10 of page 6. No new matter has been added. Favorable consideration of the above amendments and following remarks is respectfully requested.

Claims 1, 5, 20, 24, 36-41, 44 and 45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dubrul, U.S. Patent No. 5,944,701, in view of Bley et al., U.S. Patent No. 5,762,630. Applicants respectfully traverse this rejection.

Independent claims 1, 20, 36, 39 and 45 have been amended to indicate that the curved shape imparted in the guidewire by the shape memory polymer jacket is maintained even when the curved portion of the guidewire is positioned in the vessel lumen of the patient. Thus, even when the shape memory polymer jacket attains a temperature commensurate to the body temperature of the patient (e.g., 37° C), the curved shape is maintained by the shape memory polymer jacket.

It is desirable to maintain the curved shape of the guidewire in the vessel lumen so that the user of the guidewire can navigate the guidewire to a desired location within the vessel. For instance, the curvature of the distal tip of the guidewire may facilitate making a turn in the vasculature of the patient and/or negotiating branch vessels in the vasculature.

The cited prior art does not teach a guidewire with such characteristics. Dubrul teaches a self coiling guidewire. The disclosed guidewire has a flexible body which “assumes or remains in a coiled configuration at room temperature, i.e. below 30° C., usually below 25° C., and straightens at body temperature, i.e. 37° C.” Dubrul, at column 2, lines 32-36. In one embodiment, Dubrul discloses a guidewire formed of a shape memory alloy body having a straight configuration “with a coil configuration maintained by covering the body with a polymeric coating which constrains the guidewire or catheter in the coil.” Dubrul, at column 3, lines 37-39. Dubrul teaches that “[a]fter introduction to the body lumen, i.e. raising the temperature to body temperature, the shape memory alloy would convert to the superelastic

configuration (while still being in a straightened geometry), thus overcoming the coil force of the polymer coating.” Thus, it is clear that the polymer coating disclosed in Dubrul is not sufficient, nor intended to retain the coiled configuration of the guidewire when located in the vessel lumen, but rather the straightened geometry of the shape memory alloy core prevails when the guidewire is warmed to body temperature.

Furthermore, Bley et al. teach a thermally softening stylet “that softens dramatically upon insertion into a living body with a temperature of about 37° C.” Bley et al., at Abstract. As indicated in the Office Action, “Bley et al. teach the glass transition temperature to be near that of a patient’s body temperature so that the device can assume a soften state once inserted.” Office Action, January 9, 2008, at page 3. Bley et al. disclose that the stylet 113 softens almost instantaneously after it is exposed to the patient’s body temperature, making the inserted portion of the stylet “pliable and easily manipulated along the patient’s blood vessel.” Bley et al. at column 4, lines 41-42. Bley et al. teach that the preferred shape memory polymer for the stylet has a glass transition temperature of about 35° C, thus undergoes a change in stiffness as the shape memory polymer passes through the glass transition temperature as it warms to the body temperature of the patient.

It was asserted in the Office Action that “[i]t would have been obvious...to modify the polymer jacket as taught by Dubrul to be a shape memory polymer as taught by Bley et al. in order to ensure that when inserted into the body the polymeric jacket takes a soften configuration that would allow the core wire to obtain a straightened configuration.” Office Action, January 9, 2008, at page 3 (emphasis added). Even if the asserted rationale stated in the Office Action for combining the teachings of Bley et al. with those of Dubrul were true, which Applicants do not concede, the modified guidewire would not meet the limitations recited in independent claims 1, 20, 36, 39 and 45. Namely, as indicated in the Office Action, the modified polymeric coating would soften when inserted into the body to “allow the core wire to obtain a straightened configuration.” Dissimilarly, as currently claimed, the curved shape imparted in the elongate core wire by the stiffness of the shape memory polymer jacket is maintained when the guidewire is navigated through the vessel lumen of the patient, and thus when the shape memory polymer jacket is warmed to body temperature, the shape memory polymer does not pass through the glass transition temperature of the shape memory polymer.

Furthermore, a *prima facie* case of obviousness cannot be established if the proposed modification renders the prior art unsatisfactory for its intended purpose or changes the principle of operation of a reference. Applicants assert that any modification to Dubrul in which the polymer coating retains the portion of the guidewire inserted into a patient's body in a coiled configuration would change the principle of operation of the guidewire of Dubrul, and thus render the guidewire unsatisfactory for its intended purpose. Namely, the polymeric coating of the guidewire of Dubrul is intended to succumb to the forces of the shape memory alloy core of the guidewire when the temperature of the guidewire is raised to body temperature, thus straightening the guidewire by overcoming the coil force of the polymer coating. Thus, Dubrul did not intend for such a guidewire to have a curved shape when it was located in a vessel lumen. The coiled configuration is only intended to be present external of the patient's body to facilitate handling the proximal portion of the guidewire during a surgical operation. See Dubrul, at column 1, lines 43-57.

For at least these reasons, a *prima facie* case of obviousness has not been established for independent claims 1, 20, 36, 39 and 45. These claims are believed to be in condition for allowance. Claims, 5, 24, 37-38, 40-41 and 44, which depend from one of claims 1, 20, 36, 39 and 45 and include additional limitations, are also believed to be in condition for allowance. Withdrawal of the rejection is respectfully requested.

Claims 6-16 and 25-35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dubrul, U.S. Patent No. 5,944,701, in view of Bley et al., U.S. Patent No. 5,762,630, and further in view of Takahashi, U.S. Patent No. 6,485,458. Applicants respectfully traverse this rejection. As stated above, the cited combination of Dubrul and Bley et al. fails to teach or render obvious the invention claimed in independent claims 1 and 20. Claims 6-16 and 25-35 depend from one of claims 1 and 20 and include significant additional limitations. The teachings of Takahashi fail to remedy the shortcomings of Dubrul and Bley et al. For at least the reasons stated above, a *prima facie* case of obviousness has not been established with the cited combination of references. Withdrawal of the rejection is respectfully requested.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

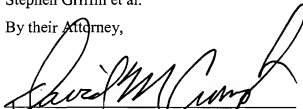
Respectfully submitted,

Stephen Griffin et al.

By their Attorney,

Date: \_\_\_\_\_

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